HIT POLICY COMMITTEE
ADOPTION/CERTIFICATION WORKGROUP

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PANEL 3: POSSIBLE APPROACHES – GOVERNMENT REPRESENTATIVE/RESEARCH

Current status of regulatory activities or other programs related to patient safety

A significant proportion of the Agency for Healthcare Quality and Research (AHRQ) $397 million FY 2010 budget is directed at patient safety and health information technology (HIT). AHRQ is implementing the Patient Safety and Quality Improvement Act of 2005, which, among other activities, establishes a new patient safety reporting program that is national in scope and offers common definitions and reporting formats for patient safety events.

AHRQ's main activities are research-related and not regulatory in nature. They include quality and safety research, as well as dissemination and implementation of proven concepts. (Two presenters at this workgroup, Drs. David Classen and James Walker, have directed HIT projects supported by AHRQ funding.) The patient safety organization program (PSO program) is, however, governed by Federal rulemaking, and AHRQ, along with the Office for Civil Rights, does have regulatory authority over provisions of the PSO program. Participation in/with PSOs is voluntary, however, so that the regulatory implications are very different from the regulatory actions of the FDA or CMS.

Considerations that may impact government efforts in the future

New and effective quality and safety concepts revealed through AHRQ's research have impacted many government efforts in the past, and it is expected that they will continue to do so. Examples include effective reduction of healthcare-associated infections, as exemplified by the Michigan *Keystone* project for central line infections, and widespread acceptance of – and mandates to use – the CAHPS (Consumer Assessment of Health Providers and Systems) surveys of consumer experience. AHRQ's research into quality and safety issues in HIT will continue, with recommended actions shared with other agencies, some of which may incorporate suggestions into policy, and with the public.

The PSO program may have a very significant impact, if its common definitions and reporting formats (Common Formats), required to be promulgated by AHRQ, are taken up by a large number of institutions and providers. These Common Formats could begin to harmonize what has been an almost completely fragmented world of patient safety reporting in which, even where commonly accepted measures exist, local IT implementation results in clinical definitions and electronic specifications that are neither comparable clinically or interoperable electronically. (Two exceptions are the CDC's National Health Safety Network [NHSN] program for healthcare-associated infections and blood adverse events and measures that derive from CMS-specified administrative data.) The Common Formats are an attempt to rationalize

this landscape in the settings for which they are being developed: hospitals, followed by skilled nursing facilities, ambulatory surgery centers, and other settings.

Approaches for reporting and tracking patient safety concerns and addressing them

AHRQ's PSO Common Formats attempt to provide the best evidence-based measures that can be developed for reporting incidents, near misses, and unsafe conditions. This testimony focuses on the Formats, as opposed to providing a detailed description of PSOs and the rules for confidentiality and privilege under which they operate. Suffice it to say, in summary, that the protected PSO reporting environment is intended to increase the volume, detail, and sophistication of reporting and enhance subsequent learning in ways that demonstrably improve patient safety.

Hallmarks of AHRQ's Common Formats include:

- Attributes
  - Scientifically supportable
  - Practical, intuitive, and useful
  - Acceptable to stakeholders
  - Conform, where possible, with accepted wisdom (e.g., CDC, WHO)
- Design considerations
  - Constructed for use at point-of-care (e.g., hospital)
  - Roll up to PSO, regional, and national levels
  - Be as short and easy to use as possible
  - Include concepts of generic reporting and specialized reporting
  - Be modular
  - Include periodic updates, version control
- Development and maintenance process
  - Expert-driven
  - Provision for continuous feedback from users
  - Open and transparent
- Content
  - Event descriptions – English language description of what is being measured
  - Specifications for reports – individual event reports and aggregate reports (by type of event)
  - Data to be collected
  - Technical specifications, including adherence to emerging Federal HIT conventions (e.g., Clinical Document Architecture [CDA]).

It is important to realize that, even with hoped-for widespread adherence to Common Formats, the PSO community will not, initially, be able to solve the problems that are typical of most patient safety data today: lack of overall surveillance of at-risk populations in order to detect all events of interest, and lack of denominators of appropriate populations at risk. These characteristics of patient safety data limit the ability to compare institutions/providers and to trend over time. However, PSO standardization is a necessary first step, will provide a greatly enhanced environment for learning, and should result in demonstrably improved care. Because

AHRQ's Common Formats are publicly available, they may be used outside the PSO environment as well as by PSOs and participating providers.

Main options for activities by government and private entities

There are many options that governments, both Federal and state, and the private sector can consider in terms of safety/quality requirements and voluntarily-provided HIT features. Areas to be addressed include:

- Design – risk assessment, testing for safety, certification for safety
- Implementation – protocols for introducing, training, implementing
- Reporting and analysis of events – standardized content, formats, suggested methodologies
- Actions based on analysis of reports – recalls, alerts, improvement actions
- Evaluation of above.

AHRQ is initiating research in many of these areas, with the intent that findings inform HIT developers as well as regulators. With respect to future development on HIT reporting under AHRQ's Common Formats, the Agency plans to develop a specialized "event-specific" Format to address IT problems in significant depth. (Currently, data for an event involving IT will include much information about general circumstances of the event, but only one specific question on whether an IT problem was implicated in a causal way.)

Advantages and disadvantages of different approaches

This issue is one that will require much thought, applied to specific proposed approaches. At a general level there are two considerations that are germane:

- It is important to harmonize the approach to HIT with that of other important areas of patient safety and quality. There is a temptation for each area to contemplate itself in great detail in isolation from other important areas, with the result that protocols, expert committees, and oversight boards are established and function in silos. The end user suffers by having incompatible, multiple data collection and compliance requirements that are inefficient at best and potentially harmful at worst. The very advantages that IT offers (modularization, harmonization, etc.) are lost.
- Experts in a specific area often assemble very long lists of issues that should, in an ideal world, be subject to scrutiny. Operationalization of systems that reflect such laudable thoroughness may be too labor-intensive to be practical. If such systems aren't adopted, are adopted but not used, or are used other than as intended, the desired improvement does not occur.

In sum, if tools/products are to be adopted on a widespread basis and used effectively to improve patient care, all approaches need to be developed with the end-user, and other relevant areas of quality and safety, in mind.